

TRANSLATION**PATENT COOPERATION TREATY****PCT****INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference BET . 7275	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/FR2004/002360	International filing date (day/month/year) 17 . 09 . 2004	Priority date (day/month/year) 18 . 09 . 2003
International Patent Classification (IPC) or national classification and IPC A61F5/448		
Applicant B. BRAUN MEDICAL SAS		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>																									
<p>4. This report contains indications relating to the following items:</p> <table><tr><td><input checked="" type="checkbox"/></td><td>Box No. I</td><td>Basis of the report</td></tr><tr><td><input type="checkbox"/></td><td>Box No. II</td><td>Priority</td></tr><tr><td><input type="checkbox"/></td><td>Box No. III</td><td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td></tr><tr><td><input type="checkbox"/></td><td>Box No. IV</td><td>Lack of unity of invention</td></tr><tr><td><input checked="" type="checkbox"/></td><td>Box No. V</td><td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td></tr><tr><td><input type="checkbox"/></td><td>Box No. VI</td><td>Certain documents cited</td></tr><tr><td><input type="checkbox"/></td><td>Box No. VII</td><td>Certain defects in the international application</td></tr><tr><td><input checked="" type="checkbox"/></td><td>Box No. VIII</td><td>Certain observations on the international application</td></tr></table>		<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input checked="" type="checkbox"/>	Box No. VIII	Certain observations on the international application
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Date of submission of the demand	Date of completion of this report																								
Name and mailing address of the IPEA/EP	Authorized officer																								
Facsimile No.	Telephone No.																								

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/FR2004/002360

Box No. I

Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____ which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-19 _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ the claims:
- nos. 1-10 _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* _____ received by this Authority on _____
- nos.* _____ received by this Authority on _____
- ☒ the drawings:
- sheets 1/6-6/6 _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/FR2004/002360

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	<u>1-10</u>	YES
	Claims	<u></u>	NO
Inventive step (IS)	Claims	<u>8</u>	YES
	Claims	<u>1-7, 9-10</u>	NO
Industrial applicability (IA)	Claims	<u>1-10</u>	YES
	Claims	<u></u>	NO
2. Citations and explanations (Rule 70.7)			
1. Claim 1 is not clear; see Box VIII.			
<p>Furthermore, irrespective of the above-mentioned lack of clarity, the subject matter of said claim does not involve an inventive step within the meaning of PCT Article 33(3).</p> <p>In particular, document FR-A-2 396 541 (see page 7 and figures 1 to 5), which is considered to be the prior art closest to the subject matter of claim 1, describes a device connector for ostomy from which the subject matter of claim 1 differs in that it specifies that:</p> <ul style="list-style-type: none">(a) prior to use, the adhesive surface of one of the connector portions is covered by a removable protective sheet;(b) and the protective sheet has <i>the feature of being removable from the adhesive surface after the additional fastening elements have been engaged.</i> <p>The subject matter of claim 1 is therefore novel and meets the requirements of PCT Article 33(2).</p>			
1.1 However, feature (a) is a routine step for protecting an adhesive surface (see also EP-A-0 747 026), whereas			

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/FR2004/002360

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
	<p>feature (b) is not clear and does not involve a difference relative to the prior art (see Box VIII).</p> <p>The subject matter of claim 1 is therefore not inventive and fails to meet the requirements of PCT Article 33(3).</p> <p>1.2 The connector described in claim 1 can be manufactured industrially. Consequently, claim 1 meets the requirements of PCT Article 33(4).</p> <p>2. Claims 2 to 10 are dependent on claim 1 and for this reason meet the conditions of PCT Article 33(2) and 33(4).</p> <p>2.1 However, the features of claims 2, 5 and 9 are suggested in EP-A-598 625 for the same purpose.</p> <p>The feature of claim 3 is suggested in US-A-4 846 820 for the same purpose.</p> <p>The feature of claim 4 is suggested in US-A-4 636 205 for the same purpose.</p> <p>The features of claims 6, 7 and 10 are suggested in FR-A-2 396 541 for the same purpose.</p> <p>Consequently, claims 2 to 7, 9 and 10 are not inventive and fail to meet the requirements of PCT Article 33(3).</p> <p>3. The combination of the features of claim 8 with those of the claims on which said claim is dependent is neither described nor suggested by the available prior art. Consequently, claim 8 involves an inventive step and meets the requirements of PCT Article 33(3).</p>

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/FR2004/002360

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. According to the wording of claim 1, the collection bag and the fastening device do not form part of the claimed subject matter, which is limited to the connector (see lines 1 to 5 of the claim).

However, the subject matter is claimed also making reference to features of the bag and the device.

This inconsistency results in a lack of clarity within the meaning of PCT Article 6.

- 1.1 The feature "the protective sheet has the feature of being removable from the adhesive surface after the additional fastening elements have been engaged" is not a technical feature of the invention, as required by PCT Rule 6.3, but merely describes one of the possible ways of using the device.

This use is not a technical limitation of the claimed connector. Furthermore, the prior art as described in FR-A-2 396 541, for example, enables such use.

Consequently, this feature does not involve a difference and is not clear within the meaning of PCT Article 6.

- 2. The use of the term "practically" in claim 2 leads to a lack of clarity: it is not possible to understand whether the protective sheet is really entirely on one side of the swivel axis or, at least partly, on the other side also.